IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PFIZER, INC.,	)	
	)	
Plaintiff and	)	
Counterclaim Defendant,	)	
	)	
v.	)	02: 02cv1628
	)	
MYLAN LABORATORIES, INC. and	)	
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendant and	)	
Counterclaim Plaintiffs.	)	

MEMORANDUM OPINION AND ORDER OF COURT

October 18, 2006

Presently before the Court for disposition is the MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION, with brief in support filed by Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively referred to as "Mylan") (*Document Nos. 167 and 168*), the Response in Opposition filed by Pfizer, Inc. ("Pfizer") (*Document No. 172*), and the Reply Memorandum filed by Mylan (*Document No. 173*).

The issues have been fully briefed and the matter is ripe for disposition. After a careful consideration of the motion, the filings in support and opposition thereto, the memoranda of the parties, the relevant case law, and the record as a whole, the Court finds that it does not have subject matter jurisdiction over the '909 patent. Therefore, for the reasons that follow, the Motion will be granted.

BACKGROUND

The facts of the case have been amply set forth in the previous opinions rendered by the Court in this case.[1] Therefore, the Court merely provides an abridged summary of facts for the purpose of this Opinion.

This is a patent infringement action brought by Pfizer whose two patents cover an amlodipine besylate product sold under the trade name, Norvasc®: United States Patent No. 4,572,909 ("the '909 patent") and United States Patent No. 4,879,303 ("the '303 patent"). On May 22, 2002, Mylan filed an Abbreviated New Drug Application ("ANDA") in which it sought approval to sell generic amlodipine besylate. By letter dated July 23, 2002, Mylan certified pursuant to 21 C.F.R. 314.94(a)(12)(i)(A)(4) (hereinafter referred to as a "paragraph IV certification") that it was seeking approval to market its generic copy of Norvasc® prior to the expiration of the '909 and '303 patents. The application stated that to the best of Mylan's knowledge neither the '909 nor the '303 patents would be infringed by the manufacture, use or sale of the proposed generic amlodipine besylate.

On September 20, 2002, Pfizer sued Mylan for infringement of both patents pursuant to 35 U.S.C. § 271(e)(2)(A). As relief, Pfizer seeks, *inter alia,* "[a]n order preliminarily enjoining and permanently enjoining [Mylan] from making, using, selling, offering to sell, or importing into the United States the Mylan Amlodipine Tablets described in ANDA No. 76-418

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[1] *See Memorandum Opinion and Order of Court* denying Motion for Partial Summary Judgment on Invalidity of Claims 1-11 of U.S. Patent No. 4,572,909 (Document No. 143) and *Sealed Memorandum Opinion and Order of Court* dated June 29, 2006, denying Motion for Summary Judgment Striking The Defense and Dismissing the Counterclaims Relating to Inequitable Conduct (Sealed Document No. 144).

until after the expiration of the '909 patent term, . . ., and after the expiration of the '303 patent term . . ." Complaint, at 7.[2] In response, Mylan contends that certain claims of the '909 patent are invalid.

On October 4, 2005, Mylan announced that it had received final approval from the FDA of its ANDA application. To date, however, Mylan has not begun to market the generic Mylan Amlodipine Tablets described in ANDA No. 76-418.

The '909 patent expired on July 31, 2006; the '303 patent will expire in March 2007. The instant Motion to Dismiss is directed solely to the '909 patent.

STANDARD OF REVIEW

A motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure presents a procedural question, and no unique issues relating to patent law are raised by said question. Accordingly, the Court must apply Third Circuit law in resolving Mylan's motion to dismiss. *See Toxgon Corp. v. BNFL, Inc.,* 312 F.3d 1379, 1380-81 (Fed. Cir. 2002) ("We review a dismissal for lack of subject matter jurisdiction according to regional circuit law, since it is a procedural question not unique to patent law."); *Madey v. Duke Univ*., 307 F.3d 1351, 1358 (Fed. Cir .2002) (same).

Rule 12(b)(1) of the Federal Rules of Civil Procedure permits a court to dismiss a complaint for lack of subject matter jurisdiction. There are two types of Rule 12(b)(1)

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[2] Pfizer also requests "judgment providing that the effective date of any FDA approval for [Mylan] to sell . . . the Mylan Amlodipine Tablets described in the ANDA No. 76-418 be no earlier than the date on which the '909 patent term, . . . expires . . .; attorneys' fees; costs and expenses; and such further relief as this Court may determine to be just and proper. *Complaint*.

motions. The first type, a facial attack, challenges the complaint on its face. The second type, which is at issue here, attacks the factual existence of subject matter jurisdiction. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

When subject matter jurisdiction "in fact" is challenged, the district court's power to hear the case is at issue, and the court is therefore "free to weigh the evidence and satisfy itself as to the power to hear the case." *Mortensen*, 549 F.2d at 891. In such an attack pursuant to Rule 12(b)(1), "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000). When a defendant attacks a court's factual basis for exercising subject matter jurisdiction, the plaintiff must meet the burden of proving that jurisdiction is appropriate. *Id*.

With these principles in mind, the Court turns to the merits of the motion before it.

Discussion

Mylan argues that Pfizer's claims for inducing infringement and infringement of the '909 patent should be dismissed for lack of subject matter jurisdiction. According to Mylan, because the '909 patent expired on July 31, 2006, there is no longer a case or controversy with respect to the '909 patent. Undeniably, the United States Constitution limits the exercise of judicial power to "cases" and "controversies." *Aetna Life Insurance Co. of Hartford, Conn. v. Haworth*, 300 U.S. 227, 239 (1937).

It is not disputed that once a patent has expired, injunctive relief is no longer available. *Lans v. Digital Equipment Corp.,* 252 F.3d 1320, 1328 (Fed. Cir. 2001) ("The district court cannot enjoin the Computer Companies from infringing an expired patent. Thus, the district court correctly ruled that Uniboard has not stated a claim on which relief can be granted."); *Kearns v. Chrysler Corp*., 32 F.3d 1541, 1550 (Fed. Cir. 1994), *cert. denied,* 516 U.S. 1032 (1995) ("when the rights secured by a patent are no longer protectable by virtue of expiration or unenforceability, entitlement to injunctive relief becomes moot because such relief is no longer available.").

Pfizer responds that the issue of "whether the district court retains jurisdiction over a patent infringement case when the patent has expired but the period of pediatric exclusivity remains at issue has been squarely resolved by the Federal Circuit against Mylan." Br. at 9. In support of its position, Pfizer relies on two Federal Circuit court decisions*: Alza v. Mylan Laboratories, Inc.*, 391 F.3d 1365 (Fed. Cir. 2004) and *Glaxo Group Ltd. v. Apotex, Inc.,* 376 F.3d 1339 (Fed. Cir. 2004). In both of these cases, the decision of the district court was issued before the patent in question expired.

However, such is not the case in the instant matter. The '909 patent expired on July 31, 2006. Prior to its expiration, there had been no judicial determination that the '909 patent was valid and/or had been infringed. Therefore, the Court finds that both the *Alza* and *Glaxo cases* are distinguishable from the instant case and not controlling. Accordingly, Pfizer has not met its burden of proving that subject matter jurisdiction continues to exist. *Carpet Group, Int'l,* 227 F.3d at 62.

Because the '909 patent has now expired, the Court finds and rules that "the rights secured by [the] patent are no longer protectable" and "entitlement to injunctive relief becomes moot because such relief is no longer available." *Kearns v. Chrysler Corp.*, 32 F.3d 1541, 1550 (Fed. Cir. 1994), *cert. denied,* 516 U.S. 1032 (1995).

Conclusion

For the aforementioned reasons, the Court finds that because the '909 patent expired on July 31, 2006, there is no present case or controversy with respect to the '909 patent and the Court, therefore, is without subject matter jurisdiction. Accordingly, the Court will grant Mylan's Motion to Dismiss For Lack of Subject Matter Jurisdiction and will dismiss Pfizer's claim for inducing infringement and infringement of the '909 patent.

An appropriate Order follows.

McVerry, J.

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ORDER OF COURT

AND NOW, this 18th day of October, 2006, in accordance with the foregoing Memorandum Opinion, it is hereby **ORDERED**, **ADJUDGED, AND DECREED** that the Motion to Dismiss for Lack of Subject Matter Jurisdiction filed by Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. is **GRANTED.**

Pfizer, Inc.'s claims for inducing infringement and infringement of the '909 patent are hereby dismissed.

BY THE COURT:

s/Terrence F. McVerry
United States District Court Judge

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